

DETAILED ACTION

1. This Office action is in response to the reply filed on November 29, 2011. Claims 37-62 are pending. Claims 48-50 and 53 have been withdrawn. Claims 37-47, 51, 52 and 54-62 are considered in this Office action.

Claim Rejections - 35 USC 112

2. The following is a quotation of the first paragraph of 35 USC 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **(Prior rejection-maintained)** The rejection of Claims 37-47, 51, 52 and 54-62 under 35 USC 112, first paragraph, as failing to comply with the written description requirement, is ***maintained*** for the reason of record.

In response to Applicant's argument:

4. Applicants argue that the claims are adequately described because "the isoelectric point of any peptide can be lowered, regardless of its initial sequence. The lowering of the isoelectric point is what allows the peptide to have increased load onto a carrier. Applicants have described a number of ways to accomplish this goal in the specification and therefore have provided written description." (Remarks, p. 9)

5. Applicants' argument is not persuasive because the specification does not support Applicant's argument. The claim limitation specifically requires that modification of a peptide's isoelectric point must lead to a specific effect: "wherein at least one of peptide load and solubility of the conjugate consisting of the plurality of the second peptide and carrier protein is

increased as compared to a conjugate of a plurality of the first peptide and carrier protein and wherein the second peptide has a non-naturally occurring sequence”. However, the specification has shown that there are uncertainties regarding which modified peptide-carrier conjugates would have “increased peptide load and solubility”. See the discussion in Para 7 of the previous office action, and the office actions dated February 25, 2010. The specification does not show that “the lowering of the isoelectric point” of any peptides “would allow the peptide to have increased load onto a carrier”, as applicants argued. In contrast to Applicants’ argument, the specification shows that there is no nexus between the “lower pI” of peptides and “increased peptide load and solubility” on all a peptide-carrier conjugate. Importantly, the specification has provided little guidance *which* peptides of any kinds with “lower pI” would correlate with their “increased peptide load and solubility” on all carrier proteins in Claim 38. Thus, the claimed method is not adequately described. Since Applicants’ argument does not provide description of the claimed method, the rejection is therefore maintained.

Remarks

6. No claims are allowed.

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Art Unit: 1648

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BO PENG, Ph.D. whose telephone number is (571)272-5542. The examiner can normally be reached on Tu-Fri, 8:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Primary Examiner, Art Unit 1648